

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the preemptive effect of metoclopramide and aminophylline on pain after deep vitrectomy

Protocol summary

Study aim

Comparison of aminophylline with metoclopramide on reducing pain intensity after deep vitrectomy

Design

This study is a randomized clinical trial with the control group, with parallel groups, double-blinded, phase 3 conducted on 105 patients randomized with random allocation software.

Settings and conduct

Participants selected randomly using random allocation software will be divided into groups receiving metoclopramide, aminophylline, or placebo. After surgery, each group receives medication or a placebo, and then vital signs and postoperative pain will be checked at different times. Participants and clinicians will be blind to study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing pars plana deep vitrectomy (20G) surgery, Age between 18 to 75 years, Status classification I or II according to the American Society of Anesthesiologists (ASA) Status Classification System, body mass index (BMI) less than 35, ability to speak, written informed consent Exclusion criteria: History of taking corticosteroids and immunosuppressants since one month before surgery, history of allergies to metoclopramide or aminophylline, taking metoclopramide, aminophylline, or any other analgesics 24 or less than 24 hours before surgery, history of malignancy, uncontrolled diabetes, smoking cigarettes, addictive drugs, and alcohol abuse, chronic pain for more than six months, mental illness, evident preoperative anxiety or tachycardia, history of taking anti-anxiety or anti-arrhythmic medications, history of general anesthesia, by using volatile anesthetics, in the last six months

Intervention groups

Patients in the first group will receive 0.1 mg/kg of metoclopramide, and the second group will receive 4 mg/kg intravenous aminophylline. The placebo group will

receive 10 ml of normal saline solution.

Main outcome variables

The intensity of pain based on the VAS scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170716035104N5**

Registration date: **2021-10-27, 1400/08/05**

Registration timing: **retrospective**

Last update: **2021-10-27, 1400/08/05**

Update count: **0**

Registration date

2021-10-27, 1400/08/05

Registrant information

Name

Roham Nik Khah

Name of organization / entity

Medical University of Isfahan

Country

Iran (Islamic Republic of)

Phone

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admin.ycc@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-25, 1396/03/04

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

2017-05-25, 1396/03/04

Actual recruitment end date

2018-03-20, 1396/12/29

Trial completion date

2018-03-20, 1396/12/29

Scientific title

Evaluating the preemptive effect of metoclopramide and aminophylline on pain after deep vitrectomy

Public title

Aminophylline and metoclopramide in pain after vitrectomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients undergoing pars plana deep vitrectomy (20G) surgery Age between 18 to 75 years Status classification I or II according to the American Society of Anesthesiologists (ASA) Status Classification System Body mass index (BMI) less than 35 Ability to speak Written informed consent

Exclusion criteria:

History of taking corticosteroids and immunosuppressants since one month before surgery History of allergies to metoclopramide or aminophylline, Taking metoclopramide, aminophylline, or any other analgesics 24 or less than 24 hours before surgery, History of malignancy, uncontrolled diabetes, smoking cigarettes, addictive drugs, and alcohol abuse, chronic pain for more than six months, mental illness, evident preoperative anxiety or tachycardia, history of taking anti-anxiety or anti-arrhythmic medications, and a history of general anesthesia by using volatile anesthetics, in the last six months

AgeFrom **18 years** old to **75 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample sizeTarget sample size: **102**Actual sample size reached: **105****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, patients are listed according to referral to surgical centers, arranged from one to 105, respectively. These numbers are then randomly divided into three groups (each will contain 35 cases) by Random Allocation Software (available at: <http://ftp.mui.ac.ir/RA.zip>). The software is set to generate numbers in a single block, based on numeric and sequential coding with a length of three digits. By hitting the Generate key, numbers from one to 105 are randomly assigned to each of the three groups defined in this study (metoclopramide, aminophylline, and placebo). The output list is copied

from the software and will be copied in Microsoft Excel software.

Blinding (investigator's opinion)

Double blinded

Blinding description

An anesthesiologist who will be unaware of the study methods would prepare the drugs in similar syringes and label them with random numbers to be delivered to the study conductor. Patients will be also unaware of the type of medication they receive.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Ethics committee of Esfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave., Esfahan, Iran.

City

Esfahan

Province

Isfahan

Postal code

7346181746

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.MUI.REC.1396.3.217

Health conditions studied**1****Description of health condition studied**

Pain intensity after deep vitrectomy

ICD-10 code

Z98.89

ICD-10 code description

Other specified postprocedural states

Primary outcomes**1****Description**

Patient's post-operative pain intensity

Timepoint

At the beginning of admission at the recovery ward, then at 30 and 60 minutes and 2, 4, 8, 16, and 24 hours after

entering the recovery ward.

Method of measurement

The Visual Analog Scale (VAS)

Secondary outcomes

1

Description

Mean of blood pressure (mm Hg)

Timepoint

During surgery (once), in the recovery ward, and 8 hours after the surgery

Method of measurement

Clinical mercury manometer

2

Description

Heart rate (beats per minute)

Timepoint

During surgery (once), in the recovery ward, and 8 hours after the surgery

Method of measurement

Beat count by palpating distal radius pulse

3

Description

Respiratory rate (breaths per minute)

Timepoint

During surgery (once), in the recovery ward, and 8 hours after the surgery

Method of measurement

Capnometry

4

Description

Pethidine required for sedation

Timepoint

Whenever the visual analog scale scores more than 3

Method of measurement

It is measured by counting the number of pethidine injections up to the end of 24 hours after admission to the recovery ward

5

Description

The patients' satisfaction status

Timepoint

Until the end of 24 hours after entering the recovery ward

Method of measurement

Questionnaire (completely satisfied, relatively satisfied, relatively dissatisfied, and completely dissatisfied)

6

Description

Recovery time

Timepoint

Until the end of 24 hours after entering the recovery ward

Method of measurement

Timer

Intervention groups

1

Description

The first intervention group will receive 0.1 mg/kg of metoclopramide by intravenous infusion for ten minutes, 15 minutes before the end of surgery.

Category

Treatment - Drugs

2

Description

The second intervention group will receive 4 mg/kg of aminophylline by intravenous infusion for ten minutes, 15 minutes before the end of surgery.

Category

Treatment - Drugs

3

Description

Patients in the control (placebo group) will receive 10 ml of intravenous normal saline for ten minutes, 15 minutes before the end of surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Feiz hospital

Full name of responsible person

Dariush Moradi Farsani

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Feiz hospital, Modares st, Esfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Daroush Moradi Farsani

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available